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Before The

Federal Trade Commission

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Cigarettes and Related Matters

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Methods To Be Employed In Determining
Tar And Nicotine Content

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SUPPLEMENTARY OBSERVATIONS FOLLOWING

NOVEMBER 30, 1966 HEARING

The written submissions and oral discussions at the November 30, 1966 Hearing, indicate that many of those concerned had wholly different approaches, technical understanding, working knowledge of the actual use or inherent limitations or required laboratory equipment, or appreciation of the scientific predicates underlying the Cambridge Filter Method, whose modification or amplification was being considered.

This Memorandum endeavors in simple form to expose and to clarify the complex technological procedures involved in testing the amount of particulate matter (PM) and nicotine in cigarette smoke. That background must be appreciated by anyone responsible for resolving the various points relating to testing which the Commission has under consideration.

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Source: https://www.industrydocuments.ucsf.edu/docs/pznk0001

## What Is Being Measured?

Whether you call it "tar" or particulate matter (PM) (TP), the Cambridge Filter Method, and the so-called Ogg Method, employing the Cambridge Filter Method, seek to determine the non-vapor material in cigarette smoke as generated in the automatic standardized smoking of a cigarette by a machine, not by a human being, according to necessary prescribed standard technical directions.

The weight of the material so drawn in the machine smoking of the cigarette is calculated by prescribed procedures, and the weight of the nicotine in that material is determined.

The amounts of (PM) and nicotine (per filter pad assembly, with each filter pad collecting the smoke of five cigarettes, as described later), being measured either absolutely or relatively are miniscule. They are weight determined from each filter pad to the nearest 0.1 milligram.

A gram is about one-twenty-eighth of an ounce. A milligram is one-thousandth of a gram. The weighing of the filter pad, which collects PM from five machine-smoked cigarettes, to 0.1 mg, is a determination to one ten-thousandth of a gram.

Put another way, a milligram is $\frac{1}{28,000}$ of an ounce.



Source: https://www.industrydocuments.ucsf.edu/docs/pznk0001

To visualize the quantities and the possible weight differences sought to be determined, one might consider a milligram to be equivalent to a barely visible particle of sugar which when dissolved in a quart of water, an amount that could not be tasted. A comparable comparison of a 0.1 mg to a gram would be to the apparent size of a period sign to an entire page of the Federal Register. ~~What is here being talked about is a series of measurements and recorded results that by analogy deal with a three percent, or an 0.3 percent, difference between the size of a single letter and another letter set in a wholly different style of type, each letter being variously printed.~~

## What Is Not Being Measured?

The Ogg Method in fact does not, and cannot, measure either all the total particulate matter (~~PM~~), or the total nicotine, ~~in~~ from any cigarette. It measures only the ~~PM~~ and nicotine in the volume of smoke puffed through a machine on the standardized method. It does not measure the PM or nicotine in all of the smoke that any cigarette might produce when totally smoked under any and all conditions.

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The Ogg Method does not measure the volume of smoke -- or the PM or nicotine in the volume of smoke -- that any human being will draw from smoking any particular cigarette. Each smoking characteristic is leveled or averaged out by the standard method.

No individual smoker always smokes in the same fashion.

No two human smokers smoke in the same way. The speed at which one smokes varies both among smokers, and usually also varies with the same individual under different circumstances even within the same day. Some take long puffs (or draws); some take short puffs. That variation affects ~~burning temperature and~~ the PM quantity in the smoke generated.

Even with the same type of cigarette, individual smokers take a different number of puffs per cigarette depending upon the circumstances. When concentrating, or talking, the number of puffs is usually less. When listening, or required to listen, to another person talking, the number of puffs per cigarette, as well as the duration of each puff, usually increases. Smoking rates while reading a book may differ from smoking rates while viewing a television program. The number of puffs and puff duration (as well as butt length) will vary according to emotional state.



Source: https://www.industrydocuments.ucsf.edu/docs/pznk0001

Some smokers customarily put their cigarettes down in an ashtray where they burn between puffs; other smokers constantly hold cigarettes in their mouths; others hold them between their fingers.

As to butt length to which individuals smoke various types of cigarettes, as will be seen the average is given as 30 millimeters, except where the filter prevents smoking down to that length, or where the rapidity of smoking generates a high heat zone or a change in taste, and causes the smoker to discard the cigarette. But, here again, there are no constants, and there is no relationship between standardized machine smoking of cigarettes and the volume of smoke which any smoker will get in smoking down to any selected butt length. About all that is known is that tobacco itself has some filter effect.

The Ogg Method does not and cannot measure these many variations in human smoking habits. It does not measure PM or nicotine in the smoke generated while the cigarette is not being puffed. It does not measure all of the PM or nicotine in any cigarette, but only that in the smoke drawn in the ~~precise~~ standardized machine smoking according to the prescribed method.



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These basic standardizations are well understood by all technologists in talking about any testing method.

## Standardization Required And Embodied In The Ogg Method

Because of the minute quantities of PM present in smoke and the ~~inescapable~~ difficulties in impounding it on a filter pad, and measuring these minute levels, the Ogg Method, or indeed any other scientific testing method, must attempt to reduce all possible variations that will substantially affect the determinations of PM and nicotine.

No standardization of technique can eliminate human error or ineptitude. No method designed can remedy the limitations in a testing method derived from the available equipment, the precision possible in its use, or its inability to secure reproducible results.

What the Ogg Method does standardize are ~~the following:~~

Puff Frequency. One puff each 60 seconds, ± one second is essential to the method. Two factors flow from that element of standardization. The first is that whatever smoking machine is used must precisely meet this

a few of the factors — puff frequency, puff duration, and the puff volume through the filter pad — that affect the burning rate and the amount of PM and nicotine deposited.

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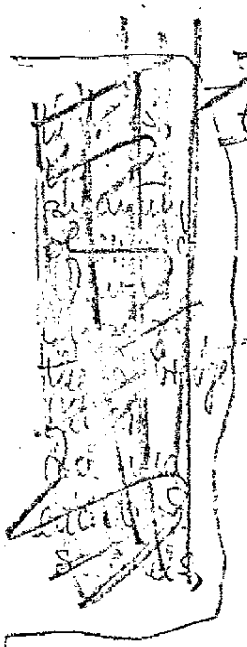
basic time requirement. The second is a reminder that this puff frequency does not reflect widely varying smoking habits, and is an average.

Puff Duration. The puff is drawn for two seconds, again within a narrow tolerance of two-tenths of a second either way. If any results are to be accurate or remotely comparable, this duration factor must be constantly watched, timed with accurate devices, and rigidly maintained by the machine.

Puff Volume. The puff volume through the filter pad controls both the burning rate and the amount of PM and nicotine deposited. The Ogg Method standardizes this volume at 35 milliliters. Again, the permitted tolerance is $\pm$ 0.5 ml. Obviously, puff volume is a basic controlling factor in the determination. There are various smoking machines that control puff volume, within the duration of each puff, in different ways. Once again, constant careful recalibration is essential. Once again, it must be remembered that the standardized puff volume may bear no direct relation to how any particular individual smokes, and is essentially an average.



The point to be remembered is that all of the difficulties and disclosed limitations in the Ogg Method

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exist even when these factors are carefully standardized. The Ogg Method of machine smoking was evolved on uniform specially prepared cigarettes. Its published description tells nothing about its use in the comparative testing of cigarettes of different brands which have varying construction, burning rate, and other variations. The Method as published discloses its variability, e.g., its limits of reproducibility, only on weight-selected cigarettes. (Compare Table 1 in the published Ogg method.) It tells nothing about smoke volume or PM or nicotine in market-derived brands of cigarettes. For example, in smoking the same brand of conditioned cigarettes, under carefully controlled conditions with experienced technicians, the number of puffs in smoking a cigarette to a specified butt length can vary from seven to ten puffs in a single machine smoking.

How Does A Smoking Machine Collect PM And Nicotine?

Inescapably, there is no substitute for anyone, particularly those without scientific laboratory training, in trying to comprehend how a smoking machine works and the difficulties in any method employing smoking machines, to do so without seeing smoking machines in operation in the hands of trained technicians. Nevertheless,

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the published Ogg Method indicates -- and even cursory viewing would confirm -- a few of the key unavoidable operating problems. These can be easily visualized by a brief description of how the job must be done.

First, it is essential to equilibrate or condition the samples of each brand of cigarettes being tested because humidity conditions at the various pickup points vary so widely. ~~A cigarette from~~ The relative humidity encountered in New Orleans may be 90 percent, ~~humid,~~ whereas ~~one from El Paso~~ in Phoenix it may be only 20 percent. In placing cigarettes on the conditioning screens, care must be exercised not to damage or fragment, or spill tobacco from, the individual cigarettes.

Each filter pad is assembled in a plastic filter holder, the parts of which must be tightly screwed together, to be leak proof.

To one side there is next attached a piece of rubber membrane with a hole cut in it. This rubber membrane must be tightly locked on with a solid rubber ring.

Each assembled filter unit must then be separately tested for leaks.

Each filter assembly must next be conditioned in the correct humidity and temperature for a sufficient period.

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Each unit assembly is then separately weighed and recorded to the nearest one-tenth of a milligram.

The assembled filter units are then placed in the smoking machine ports.

Some of the precise controls in placement and smoking may be indicated. The failure to exercise these will markedly affect the results.

To begin with, the smoking machine room must be precisely air conditioned for temperature and humidity control. Paradoxically, no smoking can be permitted in that conditioned room while the smoking machine is in operation. Automatic controls for temperature and humidity must in turn be regularly verified with manual temperature and humidity checking devices.

The air flow in the machine, both at the top vents and at the smoking ports, must be checked each day with precise instruments because such air flow directly affects the burning rate of the cigarette between puffs and can materially affect the quantity of PM deposited. Absent proper venting, the machine and the room would accumulate smoke and ~~wholly~~ distort the results.

Cardinally, the timing controls must be checked regularly, and on some types of machines even daily.

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The entire machine assembly must be regularly checked to insure that it is leak proof throughout.

Even where the smoking machines are fully calibrated, the human factors in their operation are highly variable. When inserting the cigarette in the filter holder, the ends ~~cannot~~ (should not) be bruised or broken. Where cigarettes are ~~electronically~~ electrically ignited, the lighters ~~cannot~~ (should not) be permitted to push the cigarettes against the filter pad. As Ogg notes, "Take care that butt end does not come in contact with [the Cambridge] filter disc." ~~Inserted to a definite mark - Vent cut~~

Unless automatic cut-off devices are included in the smoking machine, the problem of watching and rumbering "unders" and "overs" of butt length introduces large factors of ~~visual~~ human error. An operator has to watch, stop, and clear a number of ports within brief periods. Where automatic cut-offs are provided, carelessness in adjusting the burning threads or the springs can likewise affect the results.

For PM weighing and water and nicotine determination, other human manipulations are necessary which must be performed with both a high degree of skill and constant alert care.

The tare and second weighing of the filter unit must be performed with a chemical balance, preferably a



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refined, closed-chamber ~~electronic~~ precision balance, within the same air-conditioned room.

In the removal of the filter pad from the smoking holder, the pad must be manually folded over with a large tweezer which is then used to rub all of the remaining PM from the holder onto the filter pad. Unless this pad folding and rubbing operation is performed carefully and completely, there may be marked variations in the later determinations. As much as an entire milligram difference of the PM carried forward for latter det. can be here introduced by inexperience or ineptitude.

For water and nicotine determinations, each filter pad is next placed into a separate small flask which is then stoppered. These flasks must be carefully washed and dried after each use.

Thereafter each flask containing the separate filter pad must be thoroughly shaken with the precisely measured amount of solvent for ~~at least~~ up to an hour to get the water & nicotine into the solution. This must be accomplished by shaking machines or more reliably by a spinning agitator.

Experience demonstrates that in the chromatographic determination of water, variations can occur among different operators in the amount of solvent drawn and in

Unless the manual wiping of the smoking holder is properly performed,

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the manner of its injection into these machines, which again requires constant calibration.

In nicotine determination, precise dilutions are necessary. In virtual mass production cigarette testing, that factor may readily become a source of human error.

The calculation of results requires the use of calculating machines, and necessarily skilled operatives. Approximately two calculating machines are required in a laboratory utilizing 40 ports.

These requirements of refined equipment and experienced personnel, and the basic limitations in the Ogg Method, underlie the necessity for the suggested period of training for any personnel given the responsibility for operating a testing laboratory. Even Dr. Hammond found it necessary to offer that caution. (See Hammond, Tr. 18-19.) They dictate further that adequate personnel must be provided.

Laboratory determinations of this nature cannot be speeded up to accommodate extraneously determined dates. At the outset, there must be at least one operator for each smoking machine, one for water determination, and two for nicotine determinations if these are to be kept in balance with the smoking machines. Additional personnel

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is required for calculation and recording, and for filter unit assembly and cleaning of laboratory flasks, and maintenance.

## Limits Of Measurements Obtainable In Ogg Method

Even assuming adequate equipment and thoroughly experienced trained personnel, the available data makes clear the inherent limits in the Ogg Method. These can be talked about either as the limits of reproducibility of results within a single laboratory or as the variances in results found in the testing (the identical cigarettes) by the Ogg method among ~~in~~ different laboratories.

These inescapable variances are in the Ogg method itself, and have nothing to do with any variations in the population of cigarettes being tested. (That factor will be examined later.)

It can never be forgotten that the Ogg Method was evolved on a specially prepared uniform lot of cigarettes. Even so, the percentage coefficients of variance within single ~~the same~~ laboratory ranged between 1.2% ~~3.4%~~ and 5.9% ~~as high as 3.5%~~. Between laboratories they ~~it~~ ~~ranged as high as 10%, and~~ were never lower than 9.8%. The mean standard deviation ranged as high as 3.19 milligrams PM for non-filter cigarettes and 2.48 milligrams P.M. for filtered cigarettes.



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Indicating

In the testing of various brands of cigarettes, e.g., not a uniform specially prepared lot, ~~reported~~ has shown ~~variances yielded~~ standard deviations as high as 2.8 milligrams per cigarette determined per port.

In short, even with the ~~more~~ most accurate refined equipment and experienced personnel, the same laboratory cannot achieve reproducible results beyond these limits, stated above and if the results of two laboratories are to be compared on all brands the spreads are greater. ~~The bearing of these limits~~ The significance in the method alone will be considered in discussing sample size and reporting.

Against this summary description of the machine smoking of cigarettes and what is involved in determining and reporting PM and nicotine, some additional comments may be offered on the four questions on which the Commission has invited comment.

## Butt Length

Insofar as possible, the butt length to which cigarettes should be smoked in the smoking machine should be based on some rational criteria.

~~Recognizing that~~ In any method employing machine smoking of cigarettes to determine PM and nicotine there must be standardization of puff frequency, puff duration, and puff

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volume. These basic factors ~~in the individual smoking of cigarettes are necessarily standardized, and~~ nonetheless bear no relation to individual smoking by any human being. In that respect, as noted, these factors are when standardized initially averaged.

Because different people smoke to different butt lengths, and even the same individual will smoke to varying butt lengths depending upon the circumstances in which he is engaged, the use of an average butt length is the only rational basis to employ. To utilize predetermined average puff duration, puff volume, and puff frequency, and not to use an average butt length, creates both an illogical and unwarranted distortion in both the testing and reporting.

The recorded data makes it clear that the average butt length to which individuals smoke is somewhat in excess of 30 millimeters. No witness testified to an average of less than 30 millimeters.*/

*/ Dr. Hammond testified that his study showed an average of "approximately 30" millimeters in the United States. (Tr. p. 33) Dr. Ogg testified that data available to members of the committee at the time of his study "indicated the average butt-length in this country at that time was approximately 30 millimeters," and that in a study Dr. Ogg had recently conducted "the averages came out for non-filter cigarettes was 30.2 millimeters and for filter cigarettes was 33.2." (Tr. p. 38-39.) Dr. Hobbs testified that a butt length of no shorter than 30 to 35 millimeters "does approximate average smoking habits" (Tr. 57.) See also the Recommendations Submitted by Tennessee Eastman Company stating that the results of its study "indicated that the average butt length was at least 30 mm." (p. 1) See also the various studies referred to on p. 5-6 of the Statement to the Federal Trade Commission on Cigarette Smoking Techniques by the Celanese Corporation all of which showed an average butt length of at least 30 mm.

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Those who suggest a shorter butt length, and a different butt length for filtered cigarettes, are not unaware that doing so basically biases the comparative results under the Ogg Method largely in favor of filtered cigarettes.

It may be granted that there are presently no comprehensive studies of butt lengths, and indeed all such studies have inherent weaknesses. Butts obtained from ashtrays invariably indicate a lower average than the true ~~value~~ length to which a cigarette is smoked because a great many smokers do not wholly extinguish cigarettes, and others exert varying degrees of pressure in attempting to extinguish them. Moreover, there is evidence that most smokers cannot smoke to less than 30 millimeters without burning their fingers.**/

If 23 millimeters were selected, 90% of the filter cigarettes cannot in fact be smoked to that length. Scientifically, it is not rational to adopt a standard butt length which is not applicable to 90% of that group of cigarettes. About 99% of all cigarettes, both filtered and non-filtered, can be smoked to 30 millimeters.

Finally, there is no way of knowing what additional variances in the Ogg Method, which utilized a butt length of 30 millimeters, would be introduced by ~~any change~~ adopting a shorter butt length. In addition, →

**/ See testimony of Dr. Hobbs (Tr. p. 57).

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Any shorter butt length necessarily increases the difficulties for the operator ~~marking and inserting~~ positioning the cigarettes in the smoking machine. This is a difficult and tedious task even for the most highly skilled operator having great dexterity. Moreover, the problems of terminating the machine smoking, either by observation and withdrawal, or by automatic means, make it clear that additional variances would be introduced. Reducing the butt length would require measurable increases in sample size.

Wet Or Dry Basis

Little need be added to this point. For most cigarettes, water content ranges from 6 1/2-13% of PM collected on the Cambridge Filter. Water content among brands likewise varies even after conditioning. If the Commission is to test and record PM among brands, the failure to determine and report on a dry basis will be highly misleading.

Experience has demonstrated that test results on a dry basis contribute greater precision. As Dr. Ogg testified (Tr. 40) if the modern gas chromatographic method had been available at the time of his study, those methods would probably have been originally included to permit reporting on a dry basis.

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Reporting Of Test Results

There is no challenge that results cannot be reported beyond the precision of the testing method. A spring bathroom scale, accurate only to a pound, cannot give a person's weight in ounces or fractions of an ounce.

As to particulate matter, the errors in the Ogg procedures permit accuracy ~~only to the first two figures. This permits the reporting of TP values~~ only to the nearest milligram and not to any more finite values. What has already been noted with respect to the variances in the Ogg Method and the possibilities of human error in the mass testing of cigarettes makes it abundantly clear that any effort to report comparable ~~TP~~ PM results among different brands of cigarettes to less than the nearest whole milligram would be both unfounded and substantially misleading.

By the same token, the record makes clear that the failure to report results both on an average per puff and average per cigarette basis would create bias and have unwarranted adverse competitive effects.



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## Sampling Procedures And Number Of Cigarettes To Be Smoked

There is no need for elaborate additional statistical analysis for the consideration of sample size.

To begin with it may be assumed that picking up samples of each brand at 50 market points will permit the market sample to approach a true probability sample -- to which conventional statistical formulas may be applied. Such a market sample will not be a true probability sample, but for practical purposes, considering the other variances which must be dealt with, it may be considered sufficiently randomized to be utilized as though it were a true probability sample.

Next, there appears to be no disagreement that a confidence level of 95 percent will afford a reasonable criterion.

The determination of the number of cigarettes of each brand to be smoked to afford a pragmatically acceptable estimate for the entire population of a particular brand therefore turns on conventional statistical formulas that will adequately reflect the variations both

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in the method and in the cigarettes. The most conservative figure advanced, developed from reported industry experience, employs a standard deviation of 1.6 milligrams and yields a required sample size to be smoked of 205 cigarettes.

Statistical experts, invited carefully to study the data and make recommendations to the Commission, were in accord in advising that this suggested sample size would have to be regarded as the absolute minimum. As Dr. Herbert Arkin (an outstanding authority as indicated by his qualifications) pointed out, the variations in cigarettes within the same brand as well as the variations inherent in the Ogg Method makes it clear that the use of a standard deviation of 1.6 milligrams tends to understate the required sample size. His recommendation is that the highest reported standard deviation, rather than a value nearer the lowest, found in previous testing work, should be used, to avoid sampling and other errors. (Arkin Letter, pages 4-6.) He also notes that in most of the previous testing, cigarettes were weight selected rather than tested as they are found on the market and smoked by consumers, a factor that reduces the standard deviation, and therefore should be considered. In his judgment, therefore, a

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much larger sample would be appropriate, certainly at the outset and until a standard deviation for each brand has been determined.

On the basis of his conclusion that a sample size, determined by employing a standard deviation of 2.2 to 2.6 would be appropriate, a sample size of 307 to 519 cigarettes to be smoked would be required. (See Arkin Letter, pages 4-5, Appendix A.)

Mr. Hendricks, speaking for both himself and Dr. Alva L. Finkner, of the Research Triangle Institute, emphasized that in the application of conventional statistical formulas to the current problem, the fact that the percentage differences in PM TPP and nicotine may lie within very narrow limits, to achieve the desired precision in reporting test results would call for about 350 cigarettes of each brand to be tested. This would be essential where these percentage differences between brands were 25 percent of the comparative PM TPP values being reported. (Hendricks Statement, pages 12-14.)

Moreover, utilizing the published Reader's Digest comparative PM TPP and nicotine values for a number of different market brands, he found that the percentage of difference was very small indeed and that if in the

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brands tested by the Commission comparable small percentages of differences turned up, far larger samples would be required to be tested. (Hendricks Statement; page 14.)

No valid basis was offered at the hearing for reducing the sample size to be tested below the absolute minimum level of .205 advanced by the research scientists of the five cigarette companies.

The suggestion that sample size or butt length can somehow be related to a small fraction of the population of smokers is about as valid as suggesting that average weight estimates can be developed by limiting the observations to the skinniest people in the population and drawing a small enough sample to eliminate the contributions to the average made by the heavier or even obese people.

The only remaining point of apparent confusion resides in the failure to understand that (in addition to the disclosed variations inherent in the use of the Ogg Method by thoroughly experienced tobacco technologists) there are inescapable natural variations in cigarettes. Despite recognized close quality control in their manufacture, the tobacco in cigarettes is a natural

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product, cigarettes are mass produced on fast machinery and are distributed under highly varying climatic conditions and periods of storage. In addition, the required handling in conditioning prior to testing, and in the testing procedure itself, occasions further variations. The plain fact is that in the standardized machine smoking of the same brand of cigarettes, randomly selected from a market purchase, the rate of burning causes a difference in the number of puffs ranging from seven to ~~ten~~ ten puffs per cigarette. This in turn causes variations in the ~~TP~~ PM and nicotine deposited on the filter, and results more from the variations among cigarettes than from the limits of the method.

In short, any suggestion that every cigarette is precisely and minutely identical to every other cigarette within the same brand is fallacious. No processed natural product can be manufactured to such precise limits. Recognition of the variation in any processed agricultural product is reflected in every governmental or commercially developed grading standards.

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It is perhaps unnecessary to repeat that ~~It is perhaps unnecessary to repeat that~~ in none of the recommendations offered to the Commission respecting the employment of the Ogg-Method and of the statistical necessity for an adequate sample size for reporting results, that will inescapably be related to the entire population, is there any suggestion that any factual scientific data exists as to the relevance of ~~TP~~ PM or so-called "tar" or nicotine content in terms of health. Indeed, that basic position was underscored by the suggestion of one witness that in any reporting of results by the Commission there should be included a statement indicating that "The very small differences in tar and nicotine between different brands may not be significant, either from a statistical standpoint or from any other standpoint." (Tr. 14-15.)

Respectfully submitted,

THE AMERICAN TOBACCO COMPANY
/s/ Cyril F. Hetsko

BROWN & WILLIAMSON TOBACCO CORPORATION
/s/ Addison Q. Yeaman

LIGGETT & MYERS TOBACCO COMPANY
/s/ Frederick P. Haas

PHILIP MORRIS INCORPORATED
/s/ Paul D. Smith

R.J. REYNOLDS TOBACCO COMPANY
/s/ H. Henry Ramm

December ~~28~~ 20, 1966

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